

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 4-13, and 15-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Husar (US 2002/0061260).

Regarding claims 1, 8, 15, and 21, Husar discloses a device and method of manufacturing comprising:

A first format member comprising a first inner surface (see fig. 1 and [0139]: cover sheeting 3 is viewed as a first format member)

A second format member (see fig 14: volume receiving part 2<sup>IV</sup>) comprising a second inner surface and a well (see fig. 14: the middle well portion 4<sup>IV</sup> is being viewed as a 'well') disposed within said second inner surface

A sample fill nose (see fig. 14: right most well portion 4<sup>IV</sup> with nozzle portion 6<sup>II</sup> is being viewed as a 'sample fill nose') disposed within said second format member and extending from a sample collection opening at a first end of sample fill nose to intersect with said well at a second end of said sample fill nose

A vent (see fig. 14: the left-most well portion 4<sup>IV</sup> is being viewed as a 'vent') disposed within said second format member and extending along said second inner surface from a vent opening (transition portion 10) at a first end of said vent to intersect with said well at a second end of said vent, with said well at a second end of said vent,

Wherein said sample fill nose has a cross-section and said vent has a cross-section different from said sample fill nose cross-section (see fig. 14: as apparent from the figure, the 'vent' has cross-sections that are different from the cross-sections of the 'sample fill nose').

The vent is viewed to be configured to receive sample overflow liquid from a sample testing region.

Husar also discloses that structural elements 32 (see fig. 13 and [0187-0190]) which increase the surface and/or stimulate turbulence on a wall of the wells. These structural elements are viewed to correspond to the 'platform' required by independent claims 1, 8, 15, and 21).

Husar does not explicitly disclose that the structural elements are located on the first format member (cover sheeting 3). However, the placement of the structural elements (platforms) is strictly an engineering design choice that would have been obvious to one of ordinary skill in the art barring any unexpected results based on the exact placement of the structural elements or platforms. Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to place the structural elements (platforms) onto the first format member (cover sheeting). As a result, the structural elements (platforms) will protrude from the first format member into a well in the second format member that is configured to receive it.

For claim 4, said vent intersects with said well at an area approximately opposing an intersection of said sample fill nose with said well.

For claim 5, said platform extends from said first inner surface to a platform height and wherein said well extends within said second format member to a depth greater than said platform height, thereby further defining said sample testing region for accepting said sample.

For claims 6 and 16, Husar discloses that surface modification is further considered in defined functional fields (e.g. to functionalize surfaces in an active/reactive or passive way; amino groups, carboxyl groups, streptavidin, enzymes, among others), see [0080]. While the reagents are not explicitly disclosed as located on the structural elements (platforms), the placement of the reagents is strictly an engineering design choice that would have been obvious to one of ordinary skill in the art barring any unexpected results based on the exact placement of the structural elements or platforms. Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to place the reagents onto the surface of both the well and the platforms. Further, as the device disclosed by Husar is directed to optical testing (see [0006-0009]), it would have been obvious to one of ordinary skill in the art to functionally modify the entire surface of the interior of the device to ensure that the liquid flowing through it would contact the deposited reagents.

For claim 7, the sample testing region has a volume and further comprising a fill nose disposed within said second format member and extending from a sample collection opening at a first end to said sample testing region at a second end, said fill nose having a fill nose volume greater than said sample testing region volume.

For claim 9, figure 13 discloses cylindrical structural elements (platforms).

For claim 10, the sample fill nose is adapted to transport a volume of said sample from said sample collection opening to said sample testing region via capillary action.

For claims 11-12, Husar discloses all of the claim limitations as set forth above. However, Husar does not explicitly disclose the format wherein the volume of said sample is approximately 50 nl or within the range from approximately 5 nl to approximately 1000 nl.

Regarding limitations recited in claims 11-12 which are directed to the volume of said sample, it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states "Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim."

For claim 13, said vent opening is provided on an opposite side of said format from said sample collection opening.

For claim 17, said sample fill nose notch approximately opposes said vent notch across said well.

For claim 18, the method further comprises providing adhesive on one or both of said first and second format members (see [0097]).

For claims 19-20, the vent notch and sample fill nose notch have rectangular cross-sections (see fig. 14).

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For claims 22-24, said vent cross-section has a first area and said sample fill nose cross-section has a second area, said first area is greater than said second area.

For claim 25, said platform extends in a direction substantially perpendicular to said inner surface.

### ***Response to Arguments***

3. Applicant's arguments with respect to claims 1, 4-13, and 15-25 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMESON Q. MA whose telephone number is (571)270-7063. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571)272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JM

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797

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